REMARKS:

Claims 1, 3-6, 9-10, 12-19 and 21-23 were rejected under 35 USC 103(a) as unpatentable over Kenet.

In the section entitled 'Response to Arguments', the office action states that 'the features upon which applicant relies (i.e. an initial diagnosis being done immediately) are not recited in the rejected claims.

While applicant does not necessarily agree, in an effort to advance prosecution of this application, claims 1 and 10 have been amended to state that the method of diagnosing skin disease has an acquisition time of minutes, support for which may be found at least on page 15, lines 12-13 of the application as filed. As such, as amended, the claims state that the diagnosis of the skin disease can be done in minutes which distinguishes the instant invention from Kenet.

Regarding Kenet, it is noted that the abstract of this reference deals primarily with multispectral digital images of body surfaces which are compared to subsequent similar body images. A database is also described which contains a series of images from a lesion together with the medical history of that lesion. This database can then be used for characterizing subsequent lesions. Finally, the abstract also mentions "classifying the features of [a] lesion according to the diagnostically useful classification of pigmented skin lesions". Thus, Kenet deals primarily with temporal-spatial distribution of light-absorbing characteristics of skin lesions, in particular, the depth of their subsurface extents. In other words, changes in the multispectral (red, green blue and infra-red) characteristics of lesions are monitored over time. These images can be used to reconstruct a 3-D surface map of the lesion. This may then be used to estimate pigment depth and/or density, or to estimate features of other subsurface structures or processes (US Patent 5,836,872, column 16, lines 1-3). Thus, the majority of the document deals with methods of recording digital images of lesions such that the lesions are mapped to their particular body portion so that any changes to size, color or morphology of the lesion over time can be easily detected on comparison with the recorded images. Furthermore, multispectral images are taken so that changes to the distribution of pigment and other characteristics can also be monitored over time. Thus, Kenet teaches a method using digital photography of detecting changes in skin lesions over time. That is, Kenet teaches a method wherein the practitioner can say 'there is a skin lesion on your arm that has changed since your last visit, there needs to be a biopsy done', not a method wherein the practitioner can say ' the skin lesion on your arm is benign' as with the instant

invention.

Thus, as discussed herein, the prior art does not teach identifying the skin lesion as a specific category of skin disease within a few minutes but only that the taking of digital photos could be used to monitor changes in a skin portion over a considerably longer period of time rather than relying on memory or a doctor's drawings. That is, at best, Kenet teaches a method of analyzing digital photos for determining changes over time that indicate a skin lesion that should be examined more closely by a specialist.

That is not applicant's invention which allows for analysis of a skin lesion to determine if the skin lesion is malignant or pre-malignant (actinic keratoses, basal cell carcinoma, dyplastic nevi) or benign (banal nevi, seborrheic keratoses actinic lentigines). Previously, diagnosis was difficult and could often lesions could only be distinguished following a biopsy, which is invasive and time-consuming, unlike applicants' invention which has an acquisition time of minutes.

Thus, using the instant invention, banal nevi, which are benign, can be distinguished from dyplastic nevi which should be removed (see page 14, lines 17-19 of the application as filed). Similarly, actinic kertoses which are pre-malignant lesions can be distinguished from seborrhic keratoses which are benign (see page 14, lines 25-27 of the application as filed). In some embodiments, once a skin lesion has been identified as malignant, a biopsy is carried out to confirm that the lesion is malignant. However, when the lesion is identified as a benign skin condition, no biopsy is necessary. This is an advantage in that fewer biopsies need be carried out and as discussed on page 15 of the application as filed, the test could be performed by a non-specialist. This is not taught by Kenet. That is, Kenet identifies lesions which have changed over time and which should be biopsied; applicant teaches a method wherein the skin lesion is analyzed and categorized as malignant or benign.

Furthermore, diagnosis of a specific skin disease is not taught by the prior art. At best, Kenet suggests that this could be done (US Patent 5,836,872, column 25, lines 22-46) but does not show that it can be done, nor does Kenet specifically suggest that dysplastic melanocytic nevi; banal nevi; lentigines; actinic keratoses; seborrheic keratoses; basal cell carcinoma; and malignant melanoma could be distinguished from one another.

As discussed above, Kenet does mention a classification system which is discussed in column 25, lines 21 to 48 of US Patent 5,836,872. However, this classification system is largely prophetic and basically states that a classification method could be created,

for example, based on "a priori information about how morphologic and spectral features of pigmented cutaneous lesions correlate with microscopic pathological features thereof, a classification method may be employed by the invention that incorporates this a priori information into a classification scheme that would estimate the probability that a given cutaneous lesion belonged to a particular pathological class or diagnosis. Or for example, consider multispectral data and a priori information about the known spectral properties of certain pigments and other structures in the skin, then, a classification scheme could be employed by the invention that would classify each pixel as belonging to one, or possibly more than one, class..." Thus, while a classification scheme is envisioned, no formal classification scheme is taught. Furthermore, the envisioned scheme requires digital images for pixel analysis and/or morphological analysis of the lesion which is again not applicant's invention. Thus, Kenet suggests that it might be possible to create a classification scheme but does not demonstrate that such a scheme would work. Furthermore, the schemes suggested by Kenet require additional analysis, either digital or morphological, not found in the instant claims. Finally, US Patent 5,836,872 assumes a priori knowledge of the relationship between pigmentation and lesion histology, an assumption not required in the present invention.

As discussed previously, the differences between lesions that allow diagnosis with the present invention are based upon biochemistry, and are not morphological in nature. Thus, unlike the prior art, in applicants' invention, it is not required to postulate a link between morphology and histology. In addition, the present invention is able to classify non-pigmented lesions, in addition to pigmented lesions.

In summary, applicant teaches a method wherein a skin lesion and a control region are compared and the skin lesion is classified as a specific malignant lesion or as a specific benign lesion based on this comparison. As stated in the amended claims, this method has an acquisition time of minutes, meaning that diagnosis can be done in minutes. Kenet teaches a method wherein digital photos are used to identify skin lesions which have changed over time and does not teach how these lesions could be identified as malignant or benign.

Claims 7 and 20 were rejected under 35 USC 103(a) as unpatentable over Kenet in view of Jackson et al., Richards-Kortum et al., or Soller et al. It is believed that the amendments to the independent claims discussed above overcome these objections.

Claim 8 was rejected under 35 USC 103(a) as unpatentable over Kenet in view of Haaland. It is believed that the amendments to claim 1 as discussed above overcomes this

objection.

Further and more favorable consideration is respectfully requested.

Respectfully submitted

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